

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GREEN, Lawrence et al. Examiner: to be assigned

Serial No.: 10/776,209 Group Art Unit: 3751

Filed: February 12, 2004 Docket No.: 79693-010700

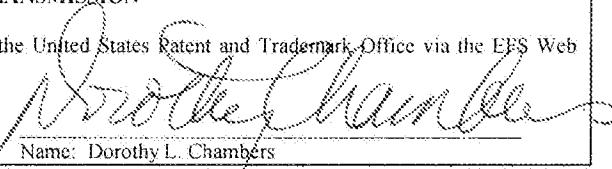
Title: MANUAL PUMP MECHANISM AND DELIVERY SYSTEM

Customer No.: 33717

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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this document is being transmitted electronically to the United States Patent and Trademark Office via the EFS Web e-Filing system on August 17, 2006.

  
Name: Dorothy L. Chambers

**PETITION TO MAKE SPECIAL UNDER MPEP 708.02 I and II -**  
**ACCELERATED EXAMINATION**

MAIL STOP: PETITION  
Commissioner for Patents  
Post Office Box 1450  
Alexandria, Virginia 22313-1450

Sir/Madam:

Applicants hereby respectfully request that this utility patent application be made special and advanced for examination under 37 CFR 1.102 and MPEP 708.02 I and II. As required:

- a) This petition to make special is accompanied by the \$130.00 fee set forth in 37 CFR 1.17(h) (authorization given to charge the petition filing fee in the amount of \$130.00 to Deposit Account No. 50-2638);
- b) Undersigned attorney for applicant/assignee duly registered before the USPTO as Patent Attorney under Registration Number 38,022 hereby makes the following statement based upon his good faith belief that the instant invention in fact

qualifies for special status, under the Code of Federal Regulations and the interpretations of the same codified in case law:

#### **I. MANUFACTURE**

i. Bio-Medical Devices, Inc., assignee of the subject application, possesses sufficient presently available capital (based upon current sales of \$20 million per year) and facilities located at 17171 Daimler Avenue, Irvine CA 92614 to manufacture the subject invention, and shall make those facilities and capital available to manufacture the device, and would appreciate issuance of U.S. Letters Patent - granted to protect this substantial investment in the instant application;

ii. Certainty that the U.S. Letters Patent shall be granted will provide an adequate comfort level to move forward, whereas if the patent is not granted the risk level with others in the marketplace (SEE Section II below, INFRINGEMENT) is substantially eroded;

iii. Bio-Medical Devices, Inc. shall manufacture the device upon issuance of the subject patent, and allowance of the instant claims, in the United States or its possessions;

iv. Assignee has a good knowledge of the art, has worked with Don Weber (Reg. No. 19,862) who made a careful and thorough review of prior art in advance of filing, which has been updated and reviewed by new counsel for this matter (GREENBERG TRAURIG LLP) and submits with this petition the two references deemed most closely related to the subject patent. See U.S. Publication No. 20060074433 and U.S. Publication No. 20060079905.

#### **II. INFRINGEMENT**

i. Subsequent to filing of the instant application, Bio-Medical Devices, Inc., assignee of the subject application, attended trade shows demonstrating the device of the subject application, at a booth with other medical device products;

ii. Employees of Boston Scientific/Scimed showed an inordinate interest in the device of the subject invention at tradeshows, and in fact filed a patent application (U.S. Publication No. 20060074433) after seeing the invention - their website indicates that they are currently offering a device based on the same for consideration;

iii. Disc-O-Tech Medical Technologies Ltd., likewise attendee at trade shows discussed similarly filed U.S. Publication No. 20060079905, and has announced a device based upon the same, likewise filing after such events;

iv. A rigid comparison of the of the devices described by the patent applications, discussed in the literature and by sales teams for the subject companies make it clear that at least claim 13 of the subject application is infringed; and,

v. A search of the art supports this conclusion, and that no other teachings supersede the claims of the instant disclosure. Copes of the references are attached.

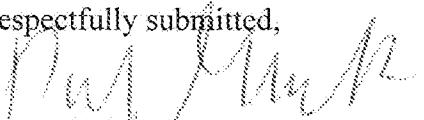
- c) A discussion of the references follows, which discussion points out, with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is patentable over the references;
- d) All of the claims in this case are directed to a single invention; and
- e) If the USPTO determines that all the claims presented are not obviously directed to a single invention, then applicant will make an election without traverse as a prerequisite to the grant of special status.

Please charge the petition filing fee in the amount of \$130.00 to Deposit Account No. 50-2638. Authorization is hereby given to charge any additional fees or credit overpayment to Deposit Account No. 50-2638.

Accordingly, it is respectfully requested that the application be accorded special status under 37 CFR 1.102, and such relief is hereby earnestly solicited.

Date: August 17, 2006

Respectfully submitted,

  
Peter J. Gluck  
Reg. No. 38,022

Customer Number 33717  
GREENBERG TRAURIG, LLP  
2450 Colorado Avenue, Suite 400E  
Santa Monica, CA 90404  
Phone: (714) 708-6500  
Fax: (310) 586-7800  
E-mail: [laipmail@gtlaw.com](mailto:laipmail@gtlaw.com)

**DISCUSSION OF REFERENCES**

Please note that this discussion of the references is not an admission that the references are in fact prior art to the invention, and Applicant expressly reserves the right to challenge any particular references discussed herein on the ground that it does not qualify as prior art *per se*.

**1. U.S. Publication No. 20060074433*****McGill et al.***

The publication demonstrates that applicants claim a pumping system which includes a fluid source, a handle-like mechanism that is located next to and allows support of the fluid source, ways to apply pressure to the fluid and to deliver a flowable compound into a vertebra.

Although the pressurizing system is rather complex and ambiguously described, everything from the configuration of the hand-piece to the description of what it is used for and does emulates the system of the present invention. However, the McGill reference cannot selectively apply pressure as the present invention does. The slavish copying of the present invention did not overcome the selective pressure feature developed by the present inventors.

**2. U.S. Publication No. 200600779905*****Beyar et al.***

The Beyar publication claims a broad range of materials and describes generically processes and sets of equipment for delivery material into a vertebra and cementing the same, such as could not be performed without the claimed system of the present invention. The batteries and pneumatics of this system have been improved by the instant invention, while the claims ostensively read upon the same.

Appended hereto are CONFIDENCE™ brand of marketing materials, and a 501(K) application for the cement used with the patent application's product in addition to materials from their web-site showing vertebroplasty procedures and systems co-extensive with the instant subject matter.